DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 19, 2014

Davol Incorporated
Mr. Tony John, MS
Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K133223
Trade/Device Name: XenMatrix™ AB Surgical Graft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: PIJ, FTM, OXH
Dated: August 6, 2014
Received: August 7, 2014

Dear Mr. John:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): **K133223**

Device Name: XenMatrix™ AB Surgical Graft

Intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue, including: abdominal plastic and reconstructive surgery; muscle flap reinforcement; hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias. The Rifampin and Minocycline coating has been shown in preclinical in vitro and in vivo testing to reduce or inhibit microbial colonization on the device. The claim of reduction of bacterial colonization of the device has not been established with human clinical data, nor has a clinical impact associated with this claim been demonstrated.

Prescription Use ___X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Davol Inc.
Subsidiary of C.R. Bard, Inc.
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BARD DAVOL INC. TECHNOLOGY TECHNIQUE TRAINING TRUST

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) Summary is provided per the requirements of section 807.92(c).

Submitter Information:

Company Name:	Davol Inc., Subsidiary of C. R. Bard, Inc.
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Submitter's Name:	Tony John, MS Regulatory Affairs Specialist
Date Summary Prepared:	August 25, 2014

Device Identification:

Trade Name:	XenMatrix™ AB Surgical Graft
Common/Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical Antimicrobial Agent
Device Class:	Class II
Regulation Number:	21 CFR § 878.3300
Product Code:	FTM

Predicate Device Names:

- Porcine Dermal Matrix Surgical Mesh, K081272 (Brennen Medical, LLC), FDA cleared on 31 July, 2008 – Currently marketed by Davol as XenMatrix™ Surgical Graft
- SURGISIS® Biodesign Tissue Graft, K073391 (Cook Biotech Incorporated), FDA cleared on 21 March, 2008
- Ventrio™ Light Hernia Patch with TRM Antimicrobial Coating, K113229 (Davol, Inc.), FDA cleared on 20 July, 2012

Device Description:
The XenMatrix™ AB Surgical Graft is an acellular, sterile, non-pyrogenic porcine dermal matrix for use in the reconstruction of soft tissue deficiencies. The graft is packed dry and must be hydrated in sterile saline prior to use. The thickness of the device is 1.5 to 2.3mm.

Product sizes when hydrated are:

- 6 x 6 cm
- 6 x 10 cm
- 6 x 16 cm
- 8 x 8 cm
- 10 x 10 cm
- 10 x 15 cm
- 15 x 20 cm
- 19 x 28 cm
- 19 x 35 cm
- 10 x 20 cm
- 20 x 20 cm
- 20 x 25 cm
- 10 x 28 cm
- 15 x 25 cm

The XenMatrix™ AB Surgical Graft surfaces are coated with an antimicrobial coating, which is comprised of a bioresorbable L-tyrosine succinate polymer and antimicrobial agents Rifampin and Minocycline at 180 µg/cm^2 each. The coating is shaded orange in color due to the color of the antimicrobial agents. The bioresorbable L-Tyrosine succinate polymer is essentially absorbed in 12 months based on *in vitro* studies.

The antimicrobial coating present on this device is intended to protect the graft from bacterial colonization. In preclinical studies the coating has been shown to reduce or inhibit microbial colonization of the device (please see performance data, section 5., below). The claim of reduction of bacterial colonization of the device has not been established with human clinical data, nor has a clinical impact associated with this claim been demonstrated.

Intended Use:
The XenMatrix™ AB Surgical Graft is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue, including: abdominal plastic and reconstructive surgery; muscle flap reinforcement; hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias. The Rifampin and Minocycline coating has been shown in preclinical *in vitro* and *in vivo* testing to reduce or inhibit microbial colonization on the device. The claim of reduction of bacterial colonization of the device has not been established with human clinical data, nor has a clinical impact associated with this claim been demonstrated.

Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use:
The XenMatrix™ AB Surgical Graft is similar in intended use and in technological characteristics and performance when compared to the cited predicate devices. XenMatrix™ AB and the cited predicates are intended for use in the reconstruction and repair of soft tissue deficiencies where weakness exists such as hernia repair. In addition, these devices are similar in technological characteristics with regard to sterilization, packaging and labeling.

The XenMatrix™ AB Surgical Graft and the predicate Porcine Dermal Matrix Surgical Mesh (K081272, marketed by Davol as XenMatrix™) are based on the same mesh matrix. The XenMatrix™ AB device contains a higher concentration, 180 µg/cm^2 (each drug) of the same antibacterial drug coating as the Ventrio Light Hernia Patch with TRM

Antimicrobial Coating (K113229). The Ventrio Light Hernia Patch device is a non-resorbable, synthetic surgical mesh containing 115 µg/cm^2 per Rifampin and Minocycline (each drug). Preparation, i.e., hydration, rinsing, of the XenMatrix™ AB device prior to use elutes Rifampin and Minocycline to equivalent concentrations as the comparator predicate surgical mesh. The instructions for use cite the specific hydration steps, i.e., submersion of the device in room temperature sterile saline or sterile water for at least 5 minutes but not exceeding 40 minutes, prior to surgical implantation.

The device differs from the SURGISIS Biodesign Tissue Graft (K073391) and Ventrio Light Hernia Patch with TRM Antimicrobial Coating (K113229) in material substrate.

Both XenMatrix™ AB and SURGISIS are based on porcine derived material. SURGISIS does not have any antimicrobial coating.

Where technological differences exist between the device and the predicate devices, performance testing indicates that the devices are substantially equivalent.

Performance Data:
The XenMatrix™ AB surgical mesh was evaluated in the following assessments:

1. Biocompatibility testing
   Biocompatibility testing in accordance to the current ISO 10993 series was conducted on the finished device and the results indicate that the device is biocompatible per these standards.

2. Bench testing
   Bench testing in accordance with the FDA Guidance for the Preperation of a Premarket Notification Application for a Surgical Mesh was conducted comparing the XenMatrix™ AB device with the cited predicates. The testing included the following:
   a. Physical Characteristics:
      i. Device Thickness
      ii. Device (Flexural) Stiffness
   b. Functional Characteristics:
      i. Burst Strength
      ii. Suture Pullout Strength
      iii. Tear Resistance

   Results demonstrate that the physical and functional characteristics of XenMatrix™ AB Surgical Mesh are substantially equivalent to the predicate comparator devices.

3. *In vivo* strength determinations
   The device was implanted in a 28 day, porcine evaluation and tested for strength characteristics in comparison to the cited predicate device at Time zero (T_0) and Day 28 (D_{28}). This study assessed the following characteristics of the implanted mesh:

a. Mechanical Testing
    i. Tensile Testing
    ii. Tissue in-growth Testing
    iii. Device Burst Testing
b. Percent Area Contracture
c. Peritoneal Tissue Attachments
d. Histology

Results demonstrate that the *in vivo* performance of XenMatrix™ AB Surgical Mesh is substantially equivalent to the predicate device.

4. Drug Content and Impurities of the Antimicrobial Agents Rifampin and Minocycline

   Analytical and *in vitro* testing was also performed on the device and included speed to kill, kinetic drug release (KDR), drug content and impurity, and polymer degradation testing. The test results demonstrated substantial equivalence to the predicate comparator surgical mesh with respect to these parameters.

5. Animal Testing

   An *in vivo* porcine implantation study was performed to investigate the device's mechanical strength and the host inflammatory response to the device over a 28 day duration. At 28 days, the XenMatrix™ AB surgical mesh had greater tissue-ingrowth/T-Peel Force values than the surgical mesh predicate. .The mechanical strength values (i.e., Ultimate Load/Burst Force, Peak Tensile Strength) of the graft alone were lower than the surgical mesh predicate .

   In addition, two *in vivo* dorsum-implanted rabbit infection model studies were performed. Devices were inoculated with bacteria at implantation, and at 7 days, post-implantation, bacterial colonization quantifications were conducted. At that time point the antimicrobial coating on the XenMatrix™ AB was observed to prevent bacterial colonization of the device in comparison to the surgical mesh predicate device.

   The relevance of these studies to human clinical performance outcomes has not been demonstrated.

   The correlation of these studies has not been demonstrated to be predictive of positive human clinical outcomes.

6. Human clinical data

   None.

   The claim of reduction of colonization has not been established with human clinical data, nor has a clinical impact associated with this claim been demonstrated.

Conclusion:
Results of the testing performed in support of this submission demonstrate that the XenMatrix™ AB Surgical Graft is substantially equivalent to currently marketed predicate devices. The claim of reduction of bacterial colonization of the device has not been established with human clinical data, nor has a clinical impact associated with this claim been demonstrated.